Summary of Changes to HR 2768 Made by Chairman's Amendment in the Nature of a Substitute Markup of "Medicare Regulatory and Contracting Reform Act of 2001" October 2001

Section	Page	Explanation of Change
1	2	Addition on lines 12-19 of a uniform definition of supplier in Medicare. This definition is used throughout the amendment.
2	2	Adds language on lines 30-33 requiring the Secretary to coordinate the release of new regulations affecting classes of providers.
2	3	Replaces (3) beginning on line 15 with (3)(A) and (3)(B) with rewritten language clarifying the regular timeline for publication of final regulations established by the Secretary must be published and that variations from that timeline must be announced.
2	4	Adds a new (D) requirement on lines 1-5 that the Secretary report annually to Congress on failures to comply with timeline on moving from interim final rules to final rules.
2	4	Clarifies on lines 18-20 that provisions in both final regulations and interim final regulations that are not a logical outgrowth of relevant notices of proposed rulemaking must be opened for an additional comment period.
3	5	Clarifies on lines 8-16 in rewritten (B) and (C) provisions that substantive changes shall not become effective until at least 30 days after the date the Secretary issues the substantive change, and that no action shall be taken against a provider with respect to noncompliance with the substantive change before the effective date of the change.

3	5	Adds on line 22 that guidance transmitted electronically will be treated as written guidance.
3	5	Clarifies on lines 27-28 that written guidance must have been issued by the relevant contractor with respect to the individual provider or supplier in order for the reliance on guidance provisions to apply.
3	5	On lines 36-36, expands the prohibition of 'any sanction' if provider followed written guidance to include any penalty or requirement for repayment of any amount.
3	6	Adds new (B) provision on lines 1-4 stating that recoveries resulting from technical payment errors are permissible.
4	7	Adds individuals on line 9 to the list of entities that receive payments from the medicare administrative contractors.
4	7	Clarifies on lines 11-13 that the contractor function of making payments includes the receipt, disbursement and accounting for funds.
4	7	Replaces (C) on lines 14-18 with rewritten language on the role of the contractors in providing beneficiaries with education and assistance.
4	7	Replaces (E) on lines 25-30 with rewritten language on the role of the contractors in communicating to providers.
4	7	Eliminates on lines 32-33 the cross-reference to (e) and (f).
4	8	Replaces "functions" with "activities" on line 6.
4	8	Adding on lines 23-23 language specifying that competition will take into account performance quality as well as price and other factors.

4 8 Replaces on line 35 four years with five years as the limit on non-competitive renewals. Replaces "without regards to any law requiring 4 9 competition" with a requirement for competition for the transfer of functions. 4 9 Adds language on lines 21-25 stating that the Secretary may consult with providers of services and others in developing performance requirements for medicare administrative contractors. Replaces "negligence" with "gross negligence" on line 27. 10 4 Replaces "negligence" with "gross negligence" on line 31. 4 10 4 11 Replaces "negligence" with "gross negligence" on line 6. Adds a new section (3) on lines 8 through 20 requiring the 4 11 Secretary to make payment to a medicare administrative contractor for legal expenses related to the defense of activities under the contract if due care was exercised by the contractor. 4 13 Adds a new section (ii) on lines 6-8 replacing "will" with "shall." 4 13 Strikes redundant language on the carrier responsibility for making determination and payments with respect to physician's services. 4 13 Adds new sections (vi), (vii), and (viii) on lines 22-27 that eliminate redundant authority of the Secretary to impose terms and conditions. Adds a new section (E) on lines 32-33 that strikes 4 13

		"carrier" and replaces it with "medicare administrative contractor."
4	14	Adds a new section (C) on lines 8-9 that conforms the carrier specific rules on disbursing of funds with the authority under the Medicare administrative contractors.
4	14	Clarifies on line 15-19 that "carrier responses" are replaced with "contractor responses."
4	14	Adds new (C) and (D) on line 8-11 that replace carrier with medicare administrative contractor in each instance that it appears.
4	14	Deletes an "and" on line 31.
4	15	Adds new sections (8) and (9) on lines 12-19 that replace carrier with medicare administrative contractor.
4	15	Adds new section (10) on lines 20-21 that strikes "carrier" from the term "carrier localities."
4	15	On line 35, clarifies that the Secretary's flexibility under the transition must be consistent with requirement for the competitive bidding of contracts at least every 5 years.
4	15	Eliminates section (B) as a redundant restatement of current law permission for non-competitive contracting.
4	16	Eliminates requirement for Secretary to submit technical and conforming amendments.
5	17	Adds on lines 14-15 that the Secretary shall develop the methodology for measuring contractor error rates in consultation with providers.
5	17	On line 16, changes the effective date for the development

		of a methodology to measure contractor error rates to 2003.
5	17	Adds new language on lines 32-35 requiring the report on the methodology to include an analysis of the sources of identified errors and potential changes to reduce claims error rates.
5	18	On lines 17-18 adds a provision requiring contractors to disclose on request identifying information regarding the individuals who answer provider questions.
5	18	Changes the effective date on line 31 to 2003.
5	20	Adds on lines 1-2 that all published material, in addition to frequently asked questions, must be available on internet sites.
6	22	On line 13, changes 'may provide' to 'shall provide.'
6	22	Includes new language on lines 32-33 requiring the GAO evaluation of the demonstration program to include a determination of the extent of any improper payments made through the demonstration.
6	23	Adds a requirement on lines 5-6 that providers be made aware of the cost of the technical assistance in the voluntary demonstration program before they decide to participate.
7	23	Section title on lines 16-17 is expanded to Medicare Provider Ombudsman; Medicare Beneficiary Ombudsman.
7	Med	s a section (b) on lines 22-line 8 on page 25 creating a licare Beneficiary Ombudsman and setting forth the duties of ombudsman.

7	25	On lines 9-18, authorizes the appropriation of such sums as are necessary to carry out the provisions of the provider and beneficiary ombudsmen subsections.
7	25	Adds a (d) on lines 19-29 related to the use of a central, toll-free number for individuals with questions about the program.
8	26	Adds language on lines 16-20 stating that Administrative Law Judges retain independence from HHS.
8	26	Deletes the word "opportunities" on line 27 following education and training and clarifies on lines 28-29 that the authorized funds are available for carrying out functions under this title.
8	29	Adds a new (2), lines 13-19, applying the expedited access to judicial review provisions to termination proceedings under Section 1866(h).
8	29	Clarifies on line 21 that the effective date applies to the subsection, not just to paragraph (1).
8	29	On line 36, clarifies that "first external hearing or appeal" referenced in bill as introduced refers reconsiderations conducted by qualified independent contractors.
8		Deleted (d) in the bill as introduced related to provider appeals on behalf of deceased beneficiaries.
9	30	Clarifies on lines 23-24 that in cases of extreme hardship, the Secretary can make an exception and permit periods for the repayment of overpayments to extend to 5 years.
9	31	Clarifies on lines 17-19 that payment amounts approved under repayment plans are not taken into account for the purposes of calculating hardship for subsequent

overpayments.

9	32	Changes provision on line 1 to prohibit recovery of overpayments until after the Administrative Law Judge level of appeal, rather than the reconsideration/qualified independent contractor level in the bill as introduced.
9	32	Adds lines 22-24 to state that the Secretary may permit random prepayment review to be utilized in additional circumstances, but only in accordance with standards developed and published by the Secretary in consultation with providers.
9	32	Adds a requirement on line 34 that sustained or high level of payment error be defined by the secretary by regulation.
9	33	On line 19, replaces "preliminary indication appears" with "preliminary analysis indicates."
9	35	Adds a requirement on lines 6-7 clarifying that exit conferences are to be held following audits.
9	35	On lines 19-21, adds a (iv) to require auditors to take into account the information made available by the provider at that conference.
9	37	On line 5, replace "may" include the ability to resubmit corrected claims with "shall."
11	38	Adds a new (5) on lines 28-29 requiring the Secretary to conduct appropriate outreach to physicians for education and training with respect to the guidelines.
11	38	On line 30, replace "may" make changes with "shall."
11	41	Adds a new (B) on lines 1-4 requiring the Medicare

		documentation for physician claims.
11	41	Adds a new (e) on lines 1-5 setting forth a study on appropriate coding of certain extended office visits, to determine whether physicians are more vulnerable to having claims denied if no positive diagnosis results from an evaluation, and, if the problem exists, to solicit recommendations for addressing it.
12	41	Adds a new Section 12 containing provisions (a)-(g) related to oversight of technology and coverage.
12	41	Adds (a) for improved coordination between the FDA and CMS on coverage of breakthrough technology.
12	42	Adds (b) that establishes a Council for Technology and Innovation within the Centers for Medicare and Medicaid Services.
12	42	Requires a study (c) by the General Accounting Office on the collection of external data for use in the medicare inpatient payment system.
12	43	Clarifies in (d) that the OSHA standards on bloodborne pathogens apply to public hospitals under the medicare provider agreements.
12	44	Adds (e) that requires an Institute of Medicine study on local coverage under the medicare program.
12	44	Adds (f) that limits the time required for the assignment of a specific code to 3 months.
13	45	Adds a new section (15) that contains miscellaneous provisions.

Payment Advisory Commission to conduct an analysis of the results of the study of simpler, alternative systems of Adds (a) stating that hospitals acting as reference labs have the same requirement for medicare secondary payor as independent labs.

Clarifies in (b) the application of the prudent layperson rule to Medicare fee-for-service.